

REMARKS

Amendments

Claim 1 is amended to delete superfluous language. Claims 1 and 2 are amended to correct errors in grammar. Claims 1 and 2 are also amended to expressly recite that the compound can be in the form of a mixture of enantiomers or a mixture of diastereomers, or can be in the form of a single enantiomer or a single diastereomer. See, e.g., page 91, lines 6-17.

Claim 5 is amended to recite that the compound is of Formulas III or VI, i.e., the elected Group. New claim 78 corresponds to original claim 5. Claim 55 is amended to delete superfluous language and to correct the name of the compound 1-[N-(7-Azaindolyl)-carbonylmethyl]-3-[4-methoxy-3-(3R)-tetrahydrofuranyloxyphenyl]-1H-pyrazole. In addition, claims 55-57 are amended to refer to "pharmaceutically" acceptable salts, for the sake of consistency. Claims 38, 65 and 76 are amended to correct a typographical error. Claim 68 is amended to delete drug addiction and morphine dependence. See new claim 77. Finally, claim 75 is amended to delete parenthetical expressions.

Election

In response to the Restriction Requirement, applicants hereby elect Group III, the compounds of formulas III and VI. Upon determination of allowable subject matter, applicants request rejoinder of the method claims of Group V, pursuant to MPEP §821.04.

With respect to the Election of Species Requirement, applicants hereby elect the compound 3-[(1-Cyclopentyl-3-ethylindazol)-6-yl]-1-(4-methylsulfonylbenzyl)-1H-pyrazole. See, e.g., compound (C) of Example 9 at page 117, line 16. Applicants assume the prosecution will now proceed in accordance with MPEP §803.02.

Applicants respectfully traverse the Restriction Requirement. By requiring election between Groups I-IV, the Examiner seeks to restrict within a single claim. This is improper.

By restricting within a single claim, the Examiner is, in effect, asserting that based on 35 USC §121 applicants are not entitled to have their claim 1 examined in a single examination. This is directly contrary to the rationale presented by the court in *In re Weber et al.*:

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits.

It is apparent that §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions when those inventions are found to be "independent and distinct." It does not, however, provide a basis for an examiner acting under the authority of the Commissioner to *reject* a particular claim on that same basis. [*Weber* at 331-332]

Although the Examiner has characterized his action as a Restriction, rather than a Rejection, the effect is the same. The Examiner is asserting that the authority given to the Commissioner under 35 USC §121 permits the Examiner to require that a single claim "be divided up and presented in several applications" and thus deny the applicants the right to have that single claim considered on its merits. This is exactly the action that the Court in *Weber* stated was not permitted under 35 USC §121. The Examiner's actions violate "the basic right of the applicant to claim his invention as he chooses." [*Weber* at 332]

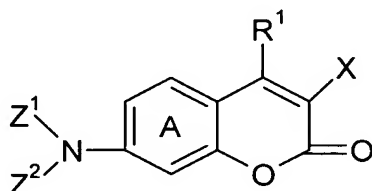
Furthermore, the Examiner has failed to explain why applicants' claim 1 is not being examined pursuant to the instructions in MPEP §803.02, entitled "Restriction - Markush Claims."

MPEP §803, entitled "Restriction - When Proper," states that "[i]nsofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP §803.02." The latter section of the MPEP states that: "[s]ince the decision in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which the applicants regard as their invention, unless the subject matter in a claim lacks unity of invention."

Thereafter, the MPEP cites *In re Harnisch*, 206 USPQ 300 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ 2d (POBA 1984). These two cases both deal with improper Markush

rejections. These two cases, *Harnisch* and *Hozumi*, both deal with improper Markush rejections. Thus, in the case of Markush claims, refusal by the Office to examine that which the applicants regard as their invention, by restricting within a Markush claim, must be a refusal based on an improper Markush rejection. In both *Harnisch* and *Hozumi*, the Court and the Board, respectively, decided that the Markush groups in question were **not improper**, and therefore restriction within a claim was not permitted. Thus, in the case of a proper Markush grouping, restriction within a claim is not permitted.

Moreover, it is clear that applicants' claims do recite a proper Markush grouping. In this regard, the decision in *In re Harnisch*, 206 USPQ 300 (CCPA 1980) is relevant. In *Harnisch*, the claimed genus of compounds was defined by the following formula:



In this formula, Z^1 was defined as being H, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring. Z^2 was defined as being H, alkyl, cycloalkyl, or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring. In addition, Z^1 and Z^2 together with the nitrogen atom could represent an optionally benz-fused heterocyclic ring which "like ring A and the alkyl, aralkyl, cycloalkyl, and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry."

Thus, as can be seen, the definition of Z^1 and Z^2 encompassed a very wide variety of structures including various nitrogen containing heterocyclic structures such as morpholinyl, piperidyl, piperazinyl, etc. Yet, the Court in *Harnisch* reversed the improper Markush rejection noting that the claimed compounds were dyes and that the subgenus claimed was not repugnant to scientific classification.

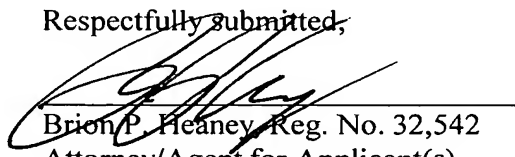
In the instant case, the compounds of applicants claimed genus are PDE4 inhibitors. The compounds of the claimed genus all contain the pyrazoles ring as a significant unchanging core structure. Furthermore, one of ordinary skill in the art would recognize that all of the compounds

of applicants' claim 1 belong to the class of pyrazoles compounds, just as the compounds of *Harnisch* belong to the class of coumarin compounds.

Thus, in the instant case, the Examiner has made a provisional election of a single species and thus examination should proceed according to §803.02. No Restriction is necessary or warranted. Thus, the Restriction between Groups I-IV should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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